

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

Children's Health Defense, *et al.*,

Plaintiffs,

v.

Food & Drug Administration, *et al.*,

Defendants.

Case No. 6:22-cv-00093-ADA-DTG

Reply in Support of Defendants' Motion to Dismiss the First Amended Complaint

TABLE OF CONTENTS

INTRODUCTION..... 1

ARGUMENT..... 2

 I. Plaintiffs’ jurisdictional burden remains unmet..... 2

 A. Plaintiffs continue to lack standing..... 2

 B. Sovereign immunity continues to bar Plaintiffs’ claims 7

 II. On their merits, Plaintiffs’ claims are still implausible 8

 III. The Court should not grant further leave to amend..... 9

CONCLUSION 10

INTRODUCTION

In May 2022, Defendants' reply in support of dismissing the original complaint opened by highlighting "three fatal flaws." *First*, "no Plaintiff possesses standing" because Plaintiffs alleged nothing more than a policy disagreement with the U.S. Food and Drug Administration ("FDA") about the emergency use authorization ("EUA") of a COVID-19 vaccine for children. *Second*, Plaintiffs "ignore the language and structure of 21 U.S.C. § 360bbb-3, which fits the exemptions for Administrative Procedure Act ("APA") review in 5 U.S.C. § 701(a)(1)–(2)," so "no waiver of sovereign immunity applies to" Plaintiffs' claims. *Third*, Plaintiffs "cannot muster an adequate legal and factual foundation for their claims," as required under the Federal Rule of Civil Procedure 12(b)(6) standard. Days later, the Court found no need to proceed beyond the first fatal flaw – lack of standing – and dismissed the complaint.

Despite ample notice to Plaintiffs and an opportunity to amend their complaint, the "three fatal flaws" identified in May remain unredressed. Plaintiffs *still* have not shown a cognizable injury fairly traceable to the challenged COVID-19 vaccine EUAs that suffices for standing. Plaintiffs *still* fail to identify an applicable waiver of sovereign immunity and to engage with the text of 21 U.S.C. § 360bbb-3. And Plaintiffs *still* fail to allege the factual and legal predicates for a plausible APA claim.

The Court should once again grant Defendants' motion to dismiss. The Court should also deny Plaintiffs further leave to amend. After two inadequate attempts to plead a justiciable case, Plaintiffs do not deserve a third.

ARGUMENT

I. Plaintiffs' jurisdictional burden remains unmet

A. Plaintiffs continue to lack standing

Standing has been – and continues to be – a threshold requirement that Plaintiffs cannot satisfy. The Court dismissed the original complaint “due to lack of standing.” May 21, 2022 Text Order. Now, “questioned” about their standing to pursue the Amended Complaint, Plaintiffs still “must explain how the elements essential to standing are met.” *Va. House of Delegates v. Bethune-Hill*, 139 S. Ct. 1945, 1951 (2019); *see* Defs.’ Mot., ECF No. 29, at 6–13. Plaintiffs’ Opposition confirms that they cannot do so.

The individual plaintiffs begin by arguing that their children “are directly threatened by” the challenged EUAs. Pls.’ Opp’n, ECF No. 30, at 13. A bare threat of harm is an “abstract injury” that is “insufficient to confer standing.” *Legacy Cmty. Health Servs., Inc. v. Smith*, 881 F.3d 358, 370 (5th Cir. 2018) (cleaned up). The individual plaintiffs must “clearly allege facts” showing that their children will suffer a “concrete and particularized injury,” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338–39 (2016) (cleaned up), and that injury must be imminent, *i.e.*, occurring within “a short timeframe,” *Attala Cnty., Miss. Branch of NAACP v. Evans*, 37 F.4th 1038, 1043 (5th Cir. 2022). None of the threatened harms mentioned in Plaintiffs’ Opposition meets that standard.

By simply declining to consent to the administration of a COVID-19 EUA vaccine to their children, the individual plaintiffs have precluded any injury from these vaccines. *See* Defs.’ Mot. 7. Although Plaintiffs worry about the “threat of being pushed out of society” and “the risk of expanding vaccine mandates,” Pls.’ Opp’n 13, they cite no mandates, either in effect or in the offing, that could apply to their children and override their parental decisions. Undeniably, neither of the challenged EUAs “compels any individual to receive the vaccine or any parent to consent to administration to their child.” Defs.’ Mot. 7. And none of the states where Plaintiffs reside have imposed an

applicable COVID-19 vaccination mandate – a point they do not contest. *See id.* 8–10 (discussing state laws).

Instead, the Shours hypothesize that they “*could* be stationed in a state” – location unknown – “that implements strict mandates” – the terms of which are unknown – “and, as a result, [their] children *could* face discrimination” – the nature and source of which are unknown. Pls.’ Opp’n 14 (emphases added). Deborah Else and Sacha Dietrich “fear that their child[ren] may be vaccinated without their consent” through the connivance of an unknown individual and an unknown medical provider’s contravention of Texas law. *See id.* 14–15. Similarly, Else and Dietrich fear their children might suffer unforeseeable medical complications and be “denied life-saving treatment” by an unknown health care provider under an unknown policy. *Id.* 14. Critically, Plaintiffs allege no facts demonstrating that these events, all of which are also contingent on the independent actions of unknown third parties and therefore not traceable to Defendants, “will occur to one of” Plaintiffs’ children imminently. *Attala Cnty.*, 37 F.4th at 1043; *see Spokeo*, 578 U.S. at 339; *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 414 (2013) (“We decline to abandon our usual reluctance to endorse standing theories that rest on speculation about the decisions of independent actors.”). And neither “subjective fear[s],” *Clapper*, 568 U.S. at 418, nor “unadorned speculation” suffices for standing, *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 44 (1976).

The individual plaintiffs also are upset that their children are exposed to messaging in favor of the EUA vaccines. *See* Pls.’ Opp’n 13. But they identify no “close historical or common-law analogue for their asserted injury,” as necessary for an intangible injury. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204 (2021). Indeed, they allege nothing more “than the psychological consequence presumably produced by observation of conduct with which one disagrees,” which “is not an injury sufficient to confer standing under Art. III.” *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 485 (1982); *see, e.g.*, Defs.’ Mot. 6 n.2 (citing cases). Furthermore, they

identify as the speakers those “not before the court,” *Simon*, 426 U.S. at 41–42, including “school administrators,” “pediatricians,” as well as “the media and other children,” Pls.’ Opp’n 13. Even if cognizable, an injury attributable to independent speakers cannot support standing to challenge the COVID-19 vaccine EUAs.

The individual plaintiffs next assert an inability “to rely on any future FDA attestations of safety and effectiveness.” Pls.’ Opp’n 15. But a valid loss-of-confidence theory still requires a “real and immediate threat of future harm.” *Funeral Consumers All., Inc. v. Serv. Corp. Int’l*, 695 F.3d 330, 343 (5th Cir. 2012). And the Amended Complaint’s “conclusory allegation[s]” about a loss of confidence are “not sufficient.” *Dragoslavic v. Ace Hardware Corp.*, 274 F. Supp. 3d 578, 583 (E.D. Tex. 2017); see Am. Compl., ECF No. 26, at ¶ 95. No plaintiff alleges they will refrain from using any FDA-approved product in the future. See *Funeral Consumers All.*, 695 F.3d at 342–43 (no standing when plaintiffs did not establish “a real and immediate threat of future harm” from future product purchases); *Brawley v. Bath & Body Works, LLC*, No. 3:18-CV-02098-S, 2019 WL 7945655, at *3 (N.D. Tex. Sept. 25, 2019).¹ Nor do Plaintiffs explain how court-ordered relief about the challenged EUAs could redress their reduced confidence in “future FDA attestations of safety and effectiveness” for *other* products. Pls.’ Opp’n 15; see *California v. Texas*, 141 S. Ct. 2104, 2115 (2021) (“To determine whether an injury is redressable, a court will consider the relationship between ‘the judicial relief requested’ and the ‘injury’ suffered.” (quoting *Allen v. Wright*, 468 U.S. 737, 753 n.19 (1984))). Ultimately, Plaintiffs’ theory amounts to an impermissible attempt to “manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending.” *Clapper*, 568 U.S. at 416; see *Food & Water*

¹ That omission fully distinguishes this case from *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956 (9th Cir. 2018), which turned on the court’s finding that the plaintiff “sufficiently alleges that she would purchase” the relevant product in the future, *id.* at 970 n.5, 971.

Watch, Inc. v. Vilsack, 808 F.3d 905, 919 (D.C. Cir. 2015) (holding that plaintiffs' desire to avoid certain poultry products due to "their subjective fear" about the adequacy of government inspection "does not give rise to standing") (quotation omitted).

Because none of the individual plaintiffs established their standing, Children's Health Defense ("CHD") necessarily lacks associational standing. Pls.' Opp'n 10; *see Ctr. for Biological Diversity v. U.S. EPA*, 937 F.3d 533, 536 (5th Cir. 2019); Defs.' Mot. 11.

CHD's bid for organizational standing fares no better. CHD continues to neglect the Fifth Circuit's clear, binding standards for organizational injuries. To reiterate: "[A]n organization does not automatically suffer a cognizable injury in fact by diverting resources in response to a defendant's conduct." *El Paso Cnty. v. Trump*, 982 F.3d 332, 343 (5th Cir. 2020); *see* Defs.' Mot. 11-12. The organization must "demonstrate[] that the diversion of resources . . . concretely and 'perceptibly impaired'" its "ability to carry out its purpose." *NAACP v. City of Kyle*, 626 F.3d 233, 239 (5th Cir. 2010) (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)). A "vague, conclusory assertion" about "divert[ed] resources is insufficient to establish" that the challenged action "'perceptibly impaired' the organization's ability to carry out its mission." *El Paso*, 982 F.3d at 344.

Plaintiffs' Opposition describes how CHD "devoted resources" to issues related to the challenged EUAs "over the past 18 months," including research, member communication, and public outreach. Pls.' Opp'n 9. But fatally, CHD cites nothing in the Amended Complaint, or in any other evidence properly before the Court, plausibly showing a "diversion of resources" that "concretely and 'perceptibly impaired'" its "ability to carry out its purpose." *City of Kyle*, 626 F.3d at 239 (quoting *Havens Realty Corp.*, 455 U.S. at 379). For instance, it still "has not 'identified any specific projects' it 'had to put on hold or otherwise curtail in order to respond to the' EUAs." Defs.' Mot. 12 (quoting *City of Kyle*, 626 F.3d at 238). And rather than show how CHD's "reaction to the allegedly unlawful conduct . . . differ[ed] from its routine activities," *El Paso Cnty.*, 982 F.3d at 344, Plaintiffs' Opposition confirms that advocacy about "public health

policies and practices that are harming our children,” like that CHD has undertaken based on its views of the EUA vaccines, *is* its mission, Pls.’ Opp’n 10–11. Because CHD’s resources are not being diverted from its core mission, it cannot claim organizational standing. *See Tenth St. Residential Ass’n v. City of Dallas*, 968 F.3d 492, 500 (5th Cir. 2020) (no organizational standing when group’s “overall mission . . . is aligned with and furthered by its efforts” in response to challenged conduct).

The other two purported injuries to CHD mentioned in Plaintiffs’ Opposition may be readily dispatched. FDA did not “ignor[e] . . . CHD’s Citizen Petition,” Pls.’ Opp’n 3, 7; to the contrary, the agency responded in great detail, *see* Defs.’ Mot. 4, 17; ECF No. 26-3, at 62–114 (FDA response). CHD identifies no issue that went unaddressed in FDA’s response, let alone an injury based on FDA’s response traceable to the challenged EUAs, so CHD’s undeveloped theory of injury falls short. *See California*, 141 S. Ct. at 2119. Likewise, CHD’s barebones assertion that Defendants “demand[ed] major social media platforms prevent [CHD] from reaching the public” and fundraising, Am. Compl. ¶ 162; *see* Pls.’ Opp’n 8, does not plausibly allege a concrete and particularized injury in fact. Nor would any independent actions by social media companies regarding CHD’s accounts be fairly traceable to FDA’s issuance of the challenged EUAs. *See Ass’n of Am. Physicians & Surgeons, Inc. v. Schiff*, 23 F.4th 1028, 1033 (D.C. Cir. 2022) (holding that organization lacked standing to sue congressman because “any actions limiting the accessibility of the Association’s web content were not taken by Representative Schiff; instead, as the amended complaint acknowledges, they were taken by independent third parties Facebook, Google, Amazon, Twitter, and YouTube”).

Equally deficient is CHD’s attempt to assert the rights of “children between the ages of six months and 11 years of age under Texas state conservatorship, who are not protected by a parent or guardian.” Pls.’ Opp’n 10. This assertion is not contained in the Amended Complaint and thus is not properly before the court. *See Cont’l Auto. Sys., Inc. v. Avanci, LLC*, 27 F.4th 326, 333 n.9 (5th Cir. 2022) (“[I]t is axiomatic that a complaint

cannot be amended by briefs in opposition to a motion to dismiss.” (quoting *In re Enron Corp. Sec., Derivative & ERISA Litig.*, 761 F. Supp. 2d 504, 566 (S.D. Tex. 2011))). In any event, CHD lacks third-party standing because it has suffered no injury itself and has “no relationship at all” with these children. *Kowalski v. Tesmer*, 543 U.S. 125, 129–31 (2004); see *Vote.Org v. Callanen*, 39 F.4th 297, 304 (5th Cir. 2022).

As before, see Defs.’ Reply, ECF No. 23, at 6, the out-of-circuit decisions Plaintiffs identify cannot salvage their standing. The Court’s “mandate [is] to follow the dictates of controlling Fifth Circuit authority,” including the cases discussed by FDA, which directly speak to organizational standing requirements. *Matamoros v. Ysleta Indep. Sch. Dist.*, 916 F. Supp. 2d 723, 729 (W.D. Tex. 2012); see *id.* (declining to “forage outside the Fifth Circuit . . . when the Fifth Circuit has spoken to the issue on multiple occasions”). In any event, the cases Plaintiffs cite, see Pls.’ Opp’n 6, 8, are irrelevant to CHD’s theories of organizational standing, see, e.g., *Pub. Citizen v. Foreman*, 631 F.2d 969, 974 n.12 (D.C. Cir. 1980) (associational standing based on injury to individual members); *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 477 (D. Md. 2019) (evaluating organization’s injury “due to agency action limiting their access to . . . information” guaranteed by statute).

Ultimately, the Amended Complaint alleges no more than a “setback to [CHD’s] abstract social interests,” which cannot confer standing. *Havens Realty Corp.*, 455 U.S. at 379. Like the individual plaintiffs, CHD lacks standing and the case should be dismissed.

B. Sovereign immunity continues to bar Plaintiffs’ claims

Apart from Plaintiffs’ inability to establish standing, sovereign immunity also imposes a jurisdictional bar. See Defs.’ Mot. 13–15. As Defendants have explained, the challenged EUAs fall within both of the exceptions to the APA’s waiver of sovereign immunity in 5 U.S.C. § 701(a)(1) and (a)(2). See *id.* Plaintiffs respond only by agreeing

that 21 U.S.C. § 360bbb-3 grants “discretion to [FDA] and the Secretary of Health and Human Services” and generally asserting that FDA’s premarket approval decisions are not traditionally committed to agency discretion. Pls.’ Opp’n 17. Fatally, they eschew any analysis of the text, structure, purpose, and history of the statutory provision specific to EUAs, which FDA showed to explicitly preclude judicial review here, *see* Defs.’ Mot. 13–15, as courts continue to recognize, *see Antunes v. Rector & Visitors of the Univ. of Va.*, No. 3:21-CV-00042, 2022 WL 4134770, at *4–5 (W.D. Va. Sept. 12, 2022) (“Plain statutory language dictates that the HHS’ vaccine emergency use authorization is ‘committed to agency discretion’” and therefore exempt from the APA’s waiver of sovereign immunity); *Doe #1-#14 v. Austin*, 572 F. Supp. 3d 1224, 1237–38 (N.D. Fla. 2021) (denying motion for preliminary injunction and observing that “the statute at issue here . . . explicitly says that EUA decisions ‘are committed to agency discretion’”).

Plaintiffs’ fallback argument under an unidentified “pre-APA review” standard, Pls.’ Opp’n 16, is most generously read as an impermissible attempt to introduce an *ultra vires* claim not pleaded in the Amended Complaint, *see Cont’l Auto. Sys.*, 27 F.4th at 333 n.9. The Court may not consider these new allegations “made in [the] opposition to the motion to dismiss.” *Id.*

II. On their merits, Plaintiffs’ claims are still implausible

Even if Plaintiffs had met their jurisdictional burden, they still face dismissal because their claims are implausible. The Amended Complaint must contain enough “well-pleaded factual allegations,” *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009), to “plausibly establish that” issuance of the challenged EUAs for children aged 6 months through 11 years was “arbitrary and capricious,” *Blanchett v. DeVos*, 490 F. Supp. 3d 26, 32 (D.D.C. 2020); *see* Defs.’ Mot. 16. In its motion to dismiss, FDA explained why each argument advanced in the Amended Complaint lacked adequate factual and legal support. *See* Defs.’ Mot. 16–20.

Plaintiffs generally maintain that FDA's consideration of the issues was inadequate but do not delve into specific flaws. *See* Pls.' Opp'n 19. This is no response to FDA's previous refutation of each purported inadequacy through citation to agency documents that Plaintiffs themselves attached to the Amended Complaint. *See* Defs.' Mot. 16–20. FDA also specifically rebutted the allegation that no emergency warranted the issuance of the challenged EUAs. *Compare* Pls.' Opp'n 19, *with* Defs.' Mot. 16–17. In addition, Plaintiffs do not dispute FDA's position that any novel arguments, which were not previously presented to the agency or raised in the record, have been waived. *See* Defs.' Mot. 19–20. Thus, Plaintiffs' claims rest upon invalid legal theories and insufficient factual support.

III. The Court should not grant further leave to amend

If the Court dismisses the Amended Complaint, it should not grant Plaintiffs another opportunity to amend. Plaintiffs' "ability to amend their pleadings is by no means unlimited." *Gonzales v. Columbia Hosp.*, 207 F. Supp. 2d 570, 573 (N.D. Tex. 2002). Among other reasons, the Court may deny further leave to amend due to the "repeated failure to cure deficiencies by amendments previously allowed" and the "futility of amendment." *Foman v. Davis*, 371 U.S. 178, 182 (1962). Both rationales are present here.

"A plaintiff's repeated failure to cure deficiencies in previous amendments is itself a basis for denying a motion for leave to amend." *Ponder Rsch. Grp., LLP v. Aquatic Navigation, Inc.*, No. 4:09-CV-322-Y, 2010 WL 1817036, at *7 (N.D. Tex. May 4, 2010) (citing *United States ex rel. Adrian v. Regents of Univ. of Cal.*, 363 F.3d 398, 403 (5th Cir. 2004)). In addition to this reply brief, Defendants detailed the flaws in Plaintiffs' case in four other briefs: their original motion to dismiss, their reply in support of the original motion to dismiss, their opposition to Plaintiffs' motion to stay, and their motion to dismiss the Amended Complaint. *See* ECF Nos. 18, 19, 23, 29. Also, the Court informed Plaintiffs of its views on those issues during the May 17, 2022 hearing. Despite these

notifications, Plaintiffs failed to “cure the[ir] pleading defects.” *Goldstein v. MCI WorldCom*, 340 F.3d 238, 254–55 (5th Cir. 2003). Because they “have had ample opportunity to plead their case,” they should “not be given leave to file a second amended complaint.” *Ponder Rsch. Grp.*, 2010 WL 1817036 at *7; *see, e.g., Soto v. City of Haltom City*, 106 F. App’x 903, 905 (5th Cir. 2004) (affirming denial of “leave to file a second amended complaint” because plaintiff “was permitted to file an amended complaint, but failed to remedy her pleading deficiencies”).

Additionally, further amendments would be futile. Futility exists when “the amended complaint would fail to state a claim upon which relief could be granted,” as analyzed under the Rule 12(b)(6) standard. *Gonzales*, 207 F. Supp. 2d at 573 (quoting *J.R. Stripling v. Jordan Production Co.*, 234 F.3d 863, 872–73 (5th Cir. 2000)). Plaintiffs have never “suggest[ed] . . . any additional facts not initially pled that could, if necessary, cure the pleading defects raised by” Defendants and the Court. *Goldstein*, 340 F.3d at 255; *see United States ex rel. Adrian*, 363 F.3d at 404. That failure renders further amendment futile. Plaintiffs had two full and fair opportunities to plead a justiciable case; no basis exists to grant them a third.

CONCLUSION

For the foregoing reasons and those contained in Defendants’ motion to dismiss the Amended Complaint, the Court should dismiss this case for lack of subject-matter jurisdiction and failure to state a claim upon which relief can be granted.

September 16, 2022

Of Counsel:

SAMUEL R. BAGENSTOS

General Counsel

U.S. Department of Health and Human
Services

Respectfully submitted,

BRIAN M. BOYNTON

Principal Deputy Assistant Attorney
General

ARUN G. RAO

Deputy Assistant Attorney General

MARK RAZA
Chief Counsel

GUSTAV W. EYLER
Director

WENDY VICENTE
Deputy Chief Counsel, Litigation

HILARY K. PERKINS
Assistant Director

JAMES ALLRED
Associate Chief Counsel
Office of the Chief Counsel
U.S. Food and Drug Administration
10903 New Hampshire Ave.
White Oak 31, Room 4564
Silver Spring, MD 20993-0002

/s/ James W. Harlow
JAMES W. HARLOW
Senior Trial Attorney
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 514-6786
(202) 514-8742 (fax)
james.w.harlow@usdoj.gov